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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,860	05/21/2007	Takashi Nishimura	3691-0133PUS1	8593

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EXAMINER
CHEN, SHIN LIN

ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
09/11/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/583,860	NISHIMURA ET AL.	
	Examiner	Art Unit	
	Shin-Lin Chen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2009 and 04 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-9 and 11-21* is/are pending in the application.

4a) Of the above claim(s) *6, 14 and 18-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7-9,11-13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendments filed 2-17-09 and 6-4-09 have been entered. Claims 1, 3-9 and 11-21 have been amended. Claims 2 and 10 have been canceled. Claims 1, 3-9 and 11-21 are pending. Claims 1, 3-5, 7-9, 11-13 and 15-17 and species WT1 are under consideration.

Election/Restrictions

Applicants reiterate the traversal on the ground(s) that groups I and II should be examined together because common technical feature is reflected, such as claims 1 is generic to both groups. This is not found persuasive because of the reasons of record set forth in the preceding Official action mailed 9-16-08.

1. This application contains claims 6, 14 and 18-21 are drawn to an invention nonelected with traverse in the reply filed on 6-9-08. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 3-5, 7, 8, 11-13 and 15-17 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention and is repeated for the reasons set forth in the

preceding Official action mailed 9-16-08. Applicant's arguments filed 2-17-09 have been fully considered but they are not persuasive.

The phrase "class I-restricted TCR" in claim 3 is vague and renders the claim indefinite. It is unclear what kind of TCR is "class I-restricted TCR". It is unclear what "class I-restricted" means. The specification fails to specifically define the phrase "class I-restricted". Claims 5, 7 and 8 depend from claim 3 but fail to clarify the indefiniteness.

The phrase "class II-restricted TCR" in claim 4 is vague and renders the claim indefinite. It is unclear what kind of TCR is "class II-restricted TCR". It is unclear what "class II-restricted" means. The specification fails to specifically define the phrase "class II-restricted". Claims 5, 7 and 8 depend from claim 4 but fail to clarify the indefiniteness.

The phrase "class I-restricted TCR" in claim 11 is vague and renders the claim indefinite. It is unclear what kind of TCR is "class I-restricted TCR". It is unclear what "class I-restricted" means. The specification fails to specifically define the phrase "class I-restricted". Claims 13 and 15-17 depend from claim 11 but fail to clarify the indefiniteness.

The phrase "class II-restricted TCR" in claim 12 is vague and renders the claim indefinite. It is unclear what kind of TCR is "class II-restricted TCR". It is unclear what "class II-restricted" means. The specification fails to specifically define the phrase "class II-restricted". Claims 13 and 15-17 depend from claim 12 but fail to clarify the indefiniteness.

Applicants cite textbook "Therapeutic Immunology" and Phan et al., 2003 and argue that the terms "class I-restricted" and "class II-restricted" are well known in the art and these terms are based on the description of the specification and/or the knowledge well-known in the art (amendment, p. 10). This is not found persuasive because of the reasons set forth in the

preceding Official action mailed 9-16-08. The cited textbook and reference refer to **MHC** class I or II-restricted TCR, however, the claims recite class I or II restricted TCR. It is still unclear what kind of TCR is "class I-restricted TCR" or "class II-restricted TCR".

The phrase "by transducing a class I-restricted T cell receptor gene…" in amended claims 3 and 11 is vague and renders the claim indefinite. It is unclear what is being transduced with the gene for a class I-restricted TCR.

The phrase "by transducing a class II-restricted T cell receptor gene…" in claims 4 and 12 is vague and renders the claim indefinite. It is unclear what is being transduced with the gene for a class II-restricted TCR.

Applicants fail to address this rejection. Therefore, the claims remain rejected for the reasons of record.

4. Claims 1, 3-5, 7-9, 11-13 and 15-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants' amendment filed 6-4-09 necessitates this new ground of rejection.

The phrase "by transducing a T cell receptor gene that recognizes a cancer-associated antigen" in claims 1 and 9 is vague and renders the claim indefinite. It is unclear what is being transduced with the T cell receptor gene. Claims 3-5, 7 and 8 depend from claim 1. Claims 11-13 and 15-17 depend from claim 9.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 3-5, 7-9, 11-13 and 15-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Tsuji et al., April 2003 (Cancer Science, Vol. 94, No. 4, p. 389-393) in view of Gaiger et al., 2008 (US Patent No. 7323181 B2) and Nishimura, Takashi, 2000 (Cancer Treatment and Host, Vol. 12, No. 4, p. 363-373, IDS-CL) and is repeated for the reasons set forth in the preceding Official action mailed 9-16-08. Applicant's arguments filed 2-17-09 have been fully considered but they are not persuasive.

Applicants argue that Tsuji discloses a method for preparing antigen-specific cytotoxic T cells by introducing a T cell receptor gene while the present invention features antigen-specific helper T cells. Tsuji does not teach or suggest the advantage of using helper T cells in the claimed process. Cytotoxic T cells and helper T cell differ in origin, recognition properties of

MHC molecules and function in stimulating the immune system. Cytotoxic T cells require MHC class I+peptide-T cell receptor+Cd3+Cd8 and helper T cells require MHC class II+peptide-T cell receptor +CD3+CD4. It was unpredictable whether the helper T cells containing a T cell receptor gene exhibit an antitumor activity. Nishimura only discloses that helper T1 cells appear to play a more important role than helper T2 cells (amendment, p. 11-13). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 9-16-08. Tsuji discloses preparation of nonspecific Tc1 cells, naïve CD8+ T cells from C57BL/6 mouse spleen and activation of those cells. Antigen-nonspecific CD8+ T cells were polyclonally expanded and transduced by retrovirus expressing 2C TCR alpha or 2C TCR beta chain to generate antigen-specific cytotoxic T lymphcytes (CTL). Nishimura teaches that it is difficult to maximize activation of antitumor immunity in vivo only by MHC class I-associated peptide, activation of class II-restricted helper T (Th) cells is also required for induction of CTL which has recognized class I-associated tumor peptide. Although Tsuji does not specifically teach using helper T cells for antitumor activity, Nishimura teaches that activation of both class II-restricted helper T (Th) cells and class I-restricted CTL (cytotoxic T lymphocyte) are important to maximize antitumor immunity. Thus, one of ordinary skill in the art at the time of the invention would have been motivated to use both helper T cells and cytotoxic T cell (CTL) transduced with TCR gene for antitumor activity. Further, the claims are directed to a process of preparing cells for cell therapy rather than a process of treating a cancer with antitumor activity. The intended use of cell therapy does not carry weight in 35 U.S.C. 103(a) rejection. Whether the helper T cells containing a T cell receptor gene exhibit an antitumor activity or not is irrelevant to the claimed invention. Thus, the claims remain rejected under 35 U.S.C. 103(a).

Conclusion

No claim is allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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